REMARKS

The Non Final Office Action mailed April 18, 2011, has been received and reviewed. Claims 85-89, 91-94, and 96-103 are pending in the subject application. All pending claims stand rejected. In particular, claims 85-89 and 96-103 were rejected under 35 U.S.C. § 112, while claims 85-89, 91-94, and 96-102 were rejected under 35 U.S.C. § 103(a).

Claims 85, 94, and 103 have been amended herein, while claims 101 and 102 have been canceled, and dependent claim 104 has been added. Accordingly, claims 85-89, 91-94, 96-100, 103, and 104 will remain pending. It is submitted that no new matter has been added by way of the present amendments. Reconsideration of the subject application is respectfully requested in view of the amendments and the following remarks.

Claim Objections

The Examiner has objected to claim 85 for reciting the phrase "whether to authorize performing a genetic test *on a when* a genetic test result is unavailable for the person." In response, the independent claim 85 has been amended to recite "on the person with a genetic test is unavailable," thus, providing a clear description within the body of the claim.

The Examiner has also objected to claim 103 for depending from canceled claim 35. In response, claim 103 is amended to depend from independent claim 94.

Rejections based on 35 U.S.C. § 112, first paragraph

The Examiner indicates that claims 85-89 and 96-103 fail to meet the requirements of 35 U.S.C. § 112, first paragraph, because it is contended that independent claims 85 and 94 do not comply with the written description requirement. In particular, the Examiner insists that claims 85 and 94 contains subject matter which was not described in the Specification

in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention.

In general, amendments to the claimed subject matter are not "new matter" within meaning of 35 U.S.C. § 132 or Rule 118 of Patent Office Rules of Practice, unless they disclose an invention, process, or apparatus not theretofore described. Further, if later-submitted material simply clarifies or completes prior disclosure, it cannot be treated as "new matter."[1] By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, "a patent application *necessarily discloses* that function, theory or advantage, even though it says nothing explicit concerning it" (emphasis added).[2] The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.[3]

Claims 85 and 94 recite, in part, a process for calculating the likelihood that a person displays a genetic mutation linked to a gene when a genetic test result value cannot be obtained from the person's EMR. In particular, with respect to claim 94, calculating the likelihood of the linked genetic mutation comprises the following steps:

a) "when demographic information about the patient is available in the EMR, determining genetic variability of the gene within the person as a function of the demographic information and basing the genetic-mutation likelihood upon the determined genetic variability;" and

[1] *Triax Co. v Hartman Metal Fabricators, Inc.*, 479 F2d 951 (1973, CA2 NY); cert. denied, 94 S. Ct. 843 (1973).
[2] *See* MPEP § 2163.07; *In re Reynolds*, 443 F.2d 384 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376 (CCPA 1973).
[3] *See id.*

b) "when demographic information about the patient is unavailable from the EMR, basing the genetic-mutation likelihood upon the genetic variability of the gene within the general population."

Referring to the Specification at paragraph [0041], the disclosure states "if the specific genetic test result information is not available for the patient, the system calculates the likelihood that the patient displays the genetic mutations linked with the gene or genes associated with the clinical agent." That is, once the genetic test result information is not found, the process proceeds to calculating a likelihood.

Initially, the step of calculating the genetic-mutation likelihood using demographic information is supported by the Specification. Referring to the Specification at paragraph [0042], the disclosure states "if demographic information about the patient is available, the system uses that information to adjust the display of the comments described above." That is, genetic variability displayed to a clinician is determined as a function of the demographic information, as recited in part (a) above. Further, an example situation disclosed in the Specification at paragraph [0051] indicates "if the patient's records included information that the patient was from the Indian subcontinent [(i.e., demographic information)], the system would consider this demographic information in determining the risk and output at step 48." Thus, it is apparent that the subject matter of Specification supports the step of determining a genetic-mutation likelihood using demographic information when available.

Next, the step of calculating the genetic-mutation likelihood using genetic variability of the gene within the general population in the absence demographic information is supported by the Specification. Referring to the Specification at paragraph [0041], the disclosure states the following in light of failing to discover genetic test result information: "Preferably, the

system accesses a database containing personal [demographic] information about the patient. If personal information relevant to the calculation of genetic variability is unavailable, the system informs the user of the genetic variability . . . relevant to the general population." That is, genetic variability displayed to a clinician is determined as a function of the genetic variability of the general population, as recited in part (b) above. Further, an example situation disclosed in the Specification at paragraph [0050] articulates this passage: "Absent other patient information [(e.g., demographic information)], to adjust the display of information at step 48, the system would inform the clinician of the 0.3% mutation in the [general] population and provide information as to the severity of the ACE at step 50." Thus, it is apparent that the subject matter of Specification supports the step of determining a genetic-mutation likelihood using general-population genetic variability when demographic information is unavailable.

Accordingly, because the previous amendments to the claims 85 and 94 are explicitly discussed, and/or inherent to, the procedure of calculating the genetic-mutation likelihood in the presence or absence of demographic information, as memorialized in the Detailed Description, this rejected subject matter is asserted to be encompassed by the scope of the Specification and does not constitute new matter.

In addition, in light of the Applicants' arguments above, the Examiner has the burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in the Applicants' disclosure a description of the invention defined by the claims.[4] As such, in rejecting the claims 85 and 94, the Examiner must set forth express findings of fact which support the lack of written description conclusion.[5]

[4] *In re Wertheim*, 541 F.2d at 263.
[5] MPEP § 2163.04(I).

Rejections based on 35 U.S.C. § 112, second paragraph

The Examiner indicates that claims 101-103 fail to meet the requirements of 35 U.S.C. 112, second paragraph, because it is contended claim 101 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states that the phrase "second data set" recited by dependent claim 101 is unclear.

Applicants point the Examiner to independent claim 94, from which claim 101 depends, that recited "when the genetic test result value is obtained from the EMR, comparing the genetic test result value to a *second data set* containing one or more polymorphism values associated with one or more atypical clinical events for the clinical agent" (emphasis added). It is clear that this second data set against which the genetic test result value is compared relates to the polymorphism/risk table that relates polymorphism information to the level of risk for a particular agent.[6]

However, in an effort to ensure that the claims are in condition for allowance and to advance prosecution, without agreeing to the merit of this rejection, claim 101 is canceled. Thus, the rejection under 35 U.S.C. 112, second paragraph, is rendered moot.

Rejections based on 35 U.S.C. § 103

A.) Applicable Authority

The teachings or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure.[7] To establish a *prima facie* case of obviousness, all the claim limitations must be taught by the prior

[6] Specification at Table 2 described in ¶¶ [0045] – [0047].
[7] *See* MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

art.[8] When determining whether a claim limitation is taught, "All words in a claim must be considered in judging the patentability of that claim against the prior art."[9] Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner: "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references."[10]

B.) Unpatentable rejection over Ichikawa in view of Evans et al. and U.S. Publication No. 2002/0049772 to Reinhoff et al. and further in view of U.S. Publication No. 2002/0038227 to Fey et al. further in view of U.S. Publication No. 2002/0110823 to Hogan in view of U.S. Patent No. 5,750,345 to Bowie and further in view of U.S. Publication No. 2003/0011646 to Levine et al.

Claims 85-89, 91-94, and 96-102 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the article in Internal Medicine, July 2000, Vol. 39, No. 7, pp. 523-524 to Ichikawa, the article in Science, October 1999, Vol. 286, pp. 487-491 to Evans et al. (hereinafter Evans), U.S. Publication No. 2002/0049772 to Reinhoff et al. (hereinafter Reinhoff), U.S. Publication No. 2002/0038227 to Fey et al. (hereinafter Fey), U.S. Publication No. 2002/0110823 to Hogan, U.S. Patent No. 5,750,345 to Bowie, and U.S. Publication No. 2003/0011646 to Levine et al. (hereinafter Levine). As the Ichikawa, Evans, Reinhoff, Fey, Hogan, Bowie, and Levine references, whether taken alone or in combination, do not describe, either expressly or inherently, each and every element of independent claims 85, 91, or 94, or the claims that depend therefrom, the Applicants respectfully consider the pending rejection of these claims overcome, as hereinafter set forth. Further, claims 101 and 102 have been canceled by

[8] MPEP § 2143.03; *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974).
[9] MPEP § 2143.03; *In re Wilson*, 57 C.C.P.A. 1029, 1032 (1970).

way of the present communication and, accordingly, the rejections of these claims have been rendered moot.

Independent claims 85 and 94 each recite a clarification of the process of "calculating the likelihood that the person displays a genetic mutation linked to the gene associated with the clinical agent," when the genetic test result value cannot be obtained from the EMR. In particular, with respect to claim 94, calculating the likelihood of the linked genetic mutation comprises the following steps:

a) "when demographic information about the patient is available in the EMR, determining genetic variability of the gene within the person as a function of the demographic information and basing the genetic-mutation likelihood upon the determined genetic variability;" and

b) "when demographic information about the patient is unavailable from the EMR, basing the genetic-mutation likelihood upon the genetic variability of the gene within the general population."

In this way, the claimed process employs two ways to calculate the likelihood of the presence of a genetic mutation: one if demographic information about the patient is available, and another if the demographic information is unavailable. Specifically, when the genetic test result value cannot be obtained, the processes of claims 85 and 94 attempt to use demographic information and then, if unavailable, use genetic variability within the general population. It is the resultant genetic-mutation likelihood that is indicated to the clinician on the UI, as more fully discussed above.

---

[10] *Ex parte Clapp*, 227 USPQ 972, 972 (Bd. Pat. App. & Inter. 1985); *see also* MPEP §706.02(j) and §2142.

The Office indicates on page 13 of the pending office action that the Bowie reference teaches a method for calculating risk of a person displaying genetic variability using the genetic variability of a general population. However, the Bowie reference does not consider each and every element of the steps (a) and (b) of claim 94 above, which are also reflected in claim 85. That is, Bowie does not include logical steps, which flow from one to another, that prefer using demographic information about the patient to determine genetic variability of the gene within the person; but, basing the genetic-mutation likelihood upon the genetic variability of the gene within the general population when demographic information about the patient is unavailable. Instead, Bowie appears to treat estimating a probability of developing a blood-related disorder equally on its prevalence in the general population, the individual's ethnic population, or the individual's sex. Moreover, Bowie does not consider defaulting to estimating a probability when an individual's genetic marker has yet to be screened. That is, Bowie may estimate the probability (i.e., predict a presence of a genetic marker) even when the individual has been previously screened for the marker, or it may not—the disclosure of Bowie is silent on this step.

Further, claim 104 has been added to the claim set to expand upon the logical steps taken by the claimed invention upon (a) determining that genetic test result values are unavailable, and (b) detecting a first demographic factor and/or a second demographic factor within the person's EMR. Support for this new claim may be found in the Specification, for example, at paragraph [0043], which deals with complex cases where the person has other relevant factors available (e.g., multiracial descent). Thus, not only does Bowie reference fail to discuss how to prioritize estimating probabilities when general population information is

available, but Bowie is silent on how to proceed if two or more demographic factors are available (e.g., both sex and ethnicity).

In view of the above, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of claim 85 and 94 be withdrawn. Further, claims 85 and 94 are believed to be in condition for allowance and such favorable action is respectfully requested. Each of claims 86-89, 96-100, 103, and 104 depend, either directly or indirectly, from one of independent claims 85 and 94, respectively. As such, these claims are believed to be in condition for allowance at least by virtue of their dependency.[11]

Independent claim 91 was previously amended to clarify the method of determining whether to automatically generate a low-risk clinical response or a high-risk clinical response, as well as the actions to be conducted for each response. In particular, the method is invoked "when the person has been exposed to one or more of the agents on the list of risk-associated agents." Upon invocation, the method involves "ascertaining whether to automatically generate a low-risk clinical response or a high-risk clinical response based on whether a dosage of the one or more agents exceeds a predetermined dangerous level." Initially, "[w]hen the person has been exposed to a dosage of the one or more agents on the list of risk-associated agents that is above the predetermined dangerous level, automatically generating the high-risk clinical response." The actions that occur upon generating a high-risk clinical response include the following:

a) "reducing the dosage of the agent to an amount below the predetermined dangerous level;" and

[11] *See* 37 C.F.R. § 1.75(c) (2006).

b) "placing an alternative order for an agent that is absent from the list of risk-associated agents."

If it is determined that a high-risk clinical response is not warranted, the method involves "automatically generating the low-risk clinical response that includes performing the actions" including the following:

a) "adding a comment to the person's electronic medical record indicating that no risks were determined from the genetic test result value;" and

b) "outputting an interpretation at the GUI of the low-risk clinical response, wherein the interpretation indicates the genetic test result value is not associated with any know risks."

In this way, the decision of whether conduct a low-risk or high-risk clinical response is based on two criteria (i.e., whether the person has been exposed to an agent on the list of risk-associated agents, and whether a dosage of the agent exceeds a predetermined dangerous level). Further, once the decision to conduct the low-risk or high-risk clinical response is made, there are specific actions that are invoked for each response.

Initially, the Examiner states that Fey does not explicitly teach ascertaining whether to automatically generate a low-risk or high-risk clinical response based on patient exposure to one or more risk-associated agents. Yet, the Office contends that the decision to implement a high-risk or low-risk clinical response is obvious simply "because the goal of the health data management system is to enable a consumer/client to better monitor their health at a genetic level."[12] Applicants assert that the general statement above is insufficient to render the specific test for selecting a high-risk and low-risk clinical response obvious. Moreover, the Examiner has still not addressed the second criteria of whether a "person has been exposed to a

[12] Office Action at pg. 16.

dosage of the one or more agents on the list of risk-associated agents that is above the predetermined dangerous level" to determine whether to automatically generate a low-risk or high-risk clinical response.

Further, once the determination of high-risk vs. low-risk made, none of the cited references disclose carrying out the specific actions "(a) reducing the dosage of the agent to an amount below the predetermined dangerous level; and (b) placing an alternative order for an agent that is absent from the list of risk-associated agents" when a high-risk clinical response is selected. Even further, once the determination above is made, none of the cited references disclose carrying out the actions "(a) adding a comment to the person's electronic medical record indicating that no risks were determined from the genetic test result value; and (b) outputting an interpretation at the GUI of the low-risk clinical response," where "the interpretation indicates the genetic test result value is not associated with any know risks," with the low-risk clinical response.

Further yet, the use of a dual-response system based of the two criteria mentioned above (the patient was exposed to a dosage of the one or more agents on the list of risk-associated agents, and the dosage is above the predetermined dangerous level) was not inherent to the provision health care at the time of invention. Instead, using these two criteria is a new and advantageous way to use the results of the processes in claim 91 to affect the treatment of the patient (i.e., implementing one specific grouping of actions (high-risk) or another specific grouping of actions (low risk)).

Last, on page 19 of the Office Action, the Examiner contends that the specific test (using the two criteria) for selecting a low-risk or a high-risk clinical response is rendered obvious because Hogan teaches generally adjusting dosages and substituting medications in

order to avoid medical complications at paragraph [0008], [0036], and [0037]. Applicants assert that recited test for determining whether a low-risk or a high-risk clinical response is warranted, as well as the particular actions associated with each response, are considerably different from Hogan's general statements above.

Further, the Office has failed to support the instant rejection under 35 U.S.C. 103 via a clear articulation of the reason(s) why the claimed invention of claim 91 would have been obvious, as required by MPEP § 2142.[13] That is, "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness,"[14] and it is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based.[15] As such, the asserted general conclusion concerning what was known without some concrete evidence in the record to support this finding will not support an obviousness rejection.[16] For instance, the hypothetical discussion of what may occur in an emergency-room setting and the Examiner's contention that generating a dual-response system in such a setting would have been obvious at the time of invention, without a more sufficient basis, are believed to be the result of impermissible hindsight instead of evidentiary support. The Office's obviousness rejection of claim 91 is therefore considered traversed; accordingly, the Office must provide documentary evidence if the rejection is to be maintained.[17]

---

[13] *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (noting that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit).
[14] *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).
[15] *In re Zurko*, 258 F.3d 1379, 1385 (Fed. Cir. 2001), *see also* MPEP § 2144.03.
[16] MPEP § 2144.03(B); *In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002).
[17] 37 C.F.R. § 1.104(d)(2).

Accordingly, for at least these reasons, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of independent claim 91, as amended, be withdrawn. Claims 92 and 93 depend from independent claim 91. As such, claims 92 and 93 are believed to be in condition for allowance at least by virtue of its dependency.[18] Consequently, withdrawal of the obviousness rejection and allowance of claims 91-93 are respectfully requested.

CONCLUSION

For at least the reasons stated above, each of claims 85-89, 91-94, 96-100, 103, and 104 is believed to be in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned—by telephone at 816.559.2136 or via email at btabor@shb.com (such communication via email is herein expressly granted)—to resolve the same prior to issuing a subsequent action. It is believed that no fee is due in conjunction with the present communication, beyond the extension fee. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.83071.

Respectfully submitted,

/Benjamin P. Tabor/

Benjamin P. Tabor
Reg. No. 60,741

BPT/tq
SHOOK, HARDY & BACON L.L.P.
2555 Grand Blvd.
Kansas City, MO 64108-2613
816-474-6550

[18] *See* 37 C.F.R. § 1.75(c) (2006).